

#5 APR 29 2001

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Hartley *et al.*

Appl. No. 09/517,466

Filed: March 2, 2000

For: **Compositions and Methods for  
Use in Recombinational Cloning  
of Nucleic Acids**



Art Unit: 1655

Examiner: Johannsen, D.

Atty. Docket: 0942.4680003/RWE/BJD

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APR 24 2001

**Letter**

Commissioner for Patents  
Washington, D.C. 20231

Sir:

Applicants submit the following documents for appropriate action by the U.S. Patent and Trademark Office:

1. First Supplemental Information Disclosure Statement (in duplicate);
2. 4 pages of Form PTO-1449 citing 21 documents;
3. A copy of each of the 21 cited documents; and
4. One return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

A handwritten signature in black ink, appearing to read "Brian J. Del Buono".

Brian J. Del Buono  
Attorney for Applicants  
Registration No. 42,473

Date: April 20, 2001

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Washington, D.C. 20005-3934  
(202) 371-2600

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Confirmation No.

Art Unit: 1655

Examiner: Johannsen, D.

Atty. Docket: 0942.4680003/RWE/BJD

**First Supplemental Information Disclosure Statement**

Commissioner for Patents  
Washington, D.C. 20231

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. The numbering on this First Supplemental Information Disclosure Statement is a continuation of the numbering in Applicants' Information Disclosure Statement filed on January 26, 2001, in connection with the above-captioned application. A copy of each document is also provided.

In accordance with 37 C.F.R. § 1.98(a)(3), Applicants' undersigned representative submits the following concise explanation of the relevance of the non-English language documents, Document Nos. AP4 and AM5, cited on Form PTO-1449.

Document No. AP4, WIPO/PCT Publication No. WO 98/53056, is in the German language. The relevance of this document may be ascertained by reference to the English language abstract appearing on the face page of this reference, and to the unverified English

language abstract (from Derwent WPI) cited as Document No. AS70 on the accompanying Form PTO-1449.

Document No. AM5, WIPO/PCT Publication No. WO 99/25851, is in the Japanese language. The relevance of this document may be ascertained by reference to the English language abstract appearing on the face page of this reference, and to the unverified English language abstract (from Derwent WPI) cited as Document No. AT70 on the accompanying Form PTO

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed within three months of the date of filing of a national application other than a continued prosecution application (CPA), OR within three months of the date of entry of the national stage as set forth in 37 C.F.R. § 1.491 in an international application, OR before the mailing date of a first Office Action on the merits OR before the mailing of a first Office Action after the filing of a request for continued examination under 37 C.F.R. § 1.114. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036. A duplicate copy of this pleading is enclosed.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Brian J. Del Buono  
Attorney for Applicants  
Registration No. 42,473

Date: April 20, 2001

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FORM PTO-1449 FIRST SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT		ATTY. DOCKET NO. 0942.4680003	APPLICATION NO. 09/517,466
		APR 20 2001 U.S. PATENT & TRADEMARK OFFICE	APPLICANT Hartley et al.
		FILING DATE March 2, 2000	GROUP 1655

## U. S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME ..	CLASS	SUB-CLASS	FILING DATE
	AA						
	AB						
	AC						
	AD						
	AE4	5,286,632	02/15/1994	Jones	435	91.2	01/09/1991
	AF4	5,650,308	07/22/1997	Baum	435	172.3	06/07/1995
	AG4	6,143,557	11/07/2000	Hartley et al.	435	320.1	01/20/1999
	AH						
	AI						
	AJ						
	AK						

## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO4	WO 94/09127	04/28/1994	PCT			Yes No
	AP4	WO 98/53056	11/26/1998	PCT			X Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR		
	AS	67	Albert, H., et al., "Site-specific integration of DNA into wild-type and mutant lox sites placed in the plant genome," <i>Plant J.</i> 7:649-659 Oxford Bios Scientific Publishers And Blackwell Scientific Publications In Association With The Society For Experimental Biology (1995).
	AT	67	Bernard, P., "Positive Selection of Recombinant DNA by CcdB," <i>BioTechniques</i> 21:320-323, Eaton Publishing Company (1996).

EXAMINER	DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449

APR 20 2001

## FIRST SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.  
0942.4680003APPLICATION NO.  
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	AH						
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	AJ						
	AK						

## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL5	WO 99/21977	05/06/1999	PCT			Yes No
	AM5	WO 99/25851	05/27/1999	PCT			X Yes No
	AN5	WO 99/55851	11/04/1999	PCT			Yes No
	AO5	WO 01/05961 A1	01/25/2001	PCT			Yes No
	AP5	WO 01/11058 A1	02/15/2001	PCT			Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	68	Dale, E.C., and Ow, D.W., "Mutations in the Cre/lox recombination site enhance the stability of recombination products: Applications for gene targeting in plants," <i>J. Cell. Biochem. 16(Suppl. F):206</i> , Abstract No. Y 108, Wiley-Liss, Inc. (1992).
AS	68	Davies, J., and Riechmann, L., "An antibody VH domain with a lox-Cre site integrated into its coding region: bacterial recombination within a single polypeptide chain," <i>FEBS Lett. 377:92-96</i> , Federation of European Biochemical Societies (1995).
AT	68	Hall, R.M., and Collis, C.M., "Mobile gene cassettes and integrons: capture and spread of genes by site-specific recombination," <i>Mol. Microbiol. 15:593-600</i> , Blackwell Scientific Publications (1995).

EXAMINER

DATE CONSIDERED

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	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

AR	69	Krafte, D.S., et al., "Stable Expression and Functional Characterization of a Human Cardiac Na <sup>+</sup> Channel Gene in Mammalian Cells," <i>J. Mol. Cell Cardiol.</i> 27:823-830, Academic Press Limited (1995).
AS	69	Lee, G., and Saito, I., "Role of nucleotide sequences of loxP spacer region in Cre-mediated recombination," <i>Gene</i> 216:55-65, Elsevier Science B.V. (August 1998).
AT	69	Venkatesh, T.V., and Redding, C.M., "Ribosomal Protein S1 and NusA Protein Complexed to Recombination Protein β of Phage λ," <i>J. Bacteriol.</i> 175:1844-1846, American Society for Microbiology (1993).

EXAMINER	DATE CONSIDERED
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**EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1442 FIRST SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT		APR 20 2001 U.S. PATENT & TRADEMARK OFFICE	ATTY. DOCKET NO. 0942.4680003	APPLICATION NO. 09/517,466
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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	70	Zahra, D.G., et al., "Selective in-vivo recombination to increase antibody library size - an improved phage display vector system," Gene 227:49-54, Elsevier Science Publishers B.V. (February 1999).
AS	70	Dialog File 351 (Derwent World Patents Index), unverified English language abstract for WIPO/PCT Publication No. WO 98/53056 (Document No. AP4); WPI Accession No. 1999-000502/199901.
AT	70	Dialog File 351 (Derwent World Patents Index), unverified English language abstract for WIPO/PCT Publication No. WO 99/25851 (Document No. AM5); WPI Accession No. 1999-347485/199929.

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